



UNITED STATES DEPARTMENT OF COMMERCE  
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NC

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
03/894,788	08/27/97	GIACOMONI	F 05/25/0213

HM12/0114

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EXAMINER  
CHANNAVAJJALA, L

ART UNIT	PAPER NUMBER
1615	

DATE MAILED:

11  
01/14/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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<b>Office Action Summary</b>	Application No. <b>08/894,788</b>	Applicant(s) <b>Paolo Giacomoni</b>
	Examiner <b>Lakshmi Channavajjala</b>	Group Art Unit <b>1615</b>

Responsive to communication(s) filed on Dec 21, 1998.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 31-38, 40-54, and 56-66 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 31-38, 40-54, and 56-66 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Receipt of Request for extension of time, Request for reconsideration and Notice of appeal, all dated 12-21-98 is acknowledged.

**Claims 31-38, 40-54 and 56-66 are currently pending. Claims 39 and 55 are canceled.**

In view of inadvertent omission of claim 48 in the previous office actions, it is necessary that the examiner allows the prosecution to continue and issue the following office action which includes claim 48.

Applicant's arguments with respect to claims 31-38, 40-54 and 56-66 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 U.S.C. § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-38, 40-54 and 56-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn et al in view of Williamson et al.

2. Hahn et al teaches a number of substances which can cause skin irritation, when applied topically. The substances includes vehicles in which active ingredients are formulated (carriers), solvents, detergents, fragrances, propellants, salicylic acid derivatives, retinoids etc., cause irritation which ranges from mild irritation to severe dermatitis conditions. Hahn et al teaches the theory that a formulation comprising an anti-irritant simultaneously with the above irritants can be used to counteract irritation caused by the above substances. However, Hahn et al teaches strontium cation as an anti-irritant and not nitric oxide (NO) synthase inhibitor in the formulation (see entire document, particularly, cols. 1-4, 10 and 11).

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Williamson et al teaches various chronic and acute inflammatory conditions such as dermatitis, sunburns, caused by various chemicals and teaches administration of NO synthase inhibitors, methyl-, dimethyl or amino substituted guanidines (column 1-3). Williamson et al also recognizes N-monomethyl-L-arginine, as a NO synthase inhibitor. Williamson et al teaches dermatitis, drug reactions, sunburn, insect bites, burns (thermal, chemical and electrical) (column 3, lines 38-45). Williamson et al also teaches pharmaceutically acceptable diluents and carriers (see col. 11, lines 35-39), which according to Hahn et al are capable of producing skin irritation.

Given the theory of Hahn et al, it is the opinion of the examiner that a skilled artisan would be motivated to incorporate any anti-irritant, in the place of strontium cation in the teachings of Hahn et al, and still be able to counteract the irritation. Because the NO synthase inhibitors of Williamson et al are capable of inhibiting chronic and acute dermatitis, a skin condition caused by chemicals (which according to Hahn et al is caused due to irritation by various chemical substances), a skilled artisan would be motivated to substitute the strontium cation of Hahn et al with NO synthase inhibitors of Williamson et al, with an expectation to inhibit the irritation by any of the above substances of Hahn et al.

#### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is (703) 308-2438. The examiner can normally be reached Monday through Friday from 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax number for this Group is (703) 305-5408.

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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. § 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of confidentiality requirements of U.S.C. § 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.**

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703-308-1234/305-2351)



Lakshmi S. Channavajjala

01/11/99



THURMAN W. PAGE  
SUPERVISORY PATENT EXAMINER  
ART UNIT 152